



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/036,768 | 11/06/2001 | Samuel Ackerman | 18242-511 (VI-11) | 4776 |
| 7590 | 05/05/2004 | | EXAMINER | |
| MINTZ, LEVIN, COHN, FERRIS, GLOVSKY and POPEO, P.C. One Financial Center Boston, MA 02111 | | | KIM, JENNIFER M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/036,768 | ACKERMAN ET AL. |
| | Examiner | Art Unit |
| | Jennifer Kim | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 January 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3-7,9-20,22-32 and 36 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3-7, 9-20, 22-32, 36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 1/23/2004

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date 4/23/04

5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

The amendment filed on January 23, 2004 have been received and entered into the application.

Action Summary

The objection of claims 7 and 20 due to typographical error is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 1, 3-7, 9, 10, 31 and 32 under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 1-7, 9-20, 22-32 and 36 of record under 35. U.S.C. 103 (a) is being maintained for the reasons stated in the previous office action.

Applicant's amendment of newly added claim 36 necessitated additional rejection presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "a non-viricidal amount" lack literal support in the specification as filed. This is New Matter rejection.

Response to Arguments

Applicants' arguments filed on January 23, 2004 have been fully considered but they are not persuasive. Applicants essentially argue neither reference describes or suggests a method in which a PBMC is treated with an aziridino compound in an amount sufficient to inhibit replication of a nucleated cell, and then administered to a patient to treat an immune disorder. This is not persuasive because Budowsky et al. teach "contacting" the biological composition with an organic solvent to inactivate viral conditions. The step of "contacting" the biological composition therefore encompasses Applicants' method step of PBMC treated with an aziridino compound and then it would be obvious to administered the treated (or contacted) composition to the immunosuppressive patient disclosed by Drobyski for an effective form of adoptive immunotherapy by leukocyte infusion. Applicants further argue that the claims require a therapeutically effective amount of the aziridino-containing agent, which is "an amount sufficient to inhibit replication of nucleic acid in a nucleated blood cell, e.g., a leukocyte. This is not persuasive because Budowsky et al. teach the selective active agent can be

used in concentration from 0.0001M to 0.05M which is overlapping effective amount (0.001% to 0.1%) utilized by the Applicants'. Therefore, the aziridino-containing agent utilized by the Applicant would be sufficient to inhibit replication leukocyte as well and therefore newly added claim 36 reciting "a non-viricidal amount" does not overcome the rejection. It is Examiner's position that absent any evidence to contrary, there would have been a reasonable expectation of success in treating graft versus host disease or allograft rejection by treating the biological composition comprising leukocyte, blood plasma with azirinino-containing compound as taught by Budowsky et al. before administering leukocyte infusion as an immunotherapy to avoid a viral contamination of the patents disclosed by Drobyski. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of January 23, 2004 is deemed proper and asserted with full force and repeated to obviate applicants' claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617